Los Alamos National Laboratory — Supplemental Instructions

Section:	**46**	**Quality Assurance**
Subject:	**46.3**	**Subcontractor Qualification**

PURPOSE: This Supplemental Instruction (SI) is to describe when a supplier's technical capabilities or quality assurance (QA) program is to be assessed or verified and how this assessment will be accomplished.

POLICY: The Laboratory shall ensure that products and services acquired conform to the quality requirements of the affected program.

SCOPE: This SI applies to all quality-affecting subcontracts in which the requester determines that a supplier should be qualified.

DEFINITIONS:

Assessment   An assessment is a planned and documented activity which determines by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, etc., and the effectiveness of implementation of a quality program. An assessment should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Assessment Plan   An assessment plan is an evaluation tool developed by the lead auditor of the BUS Quality Support Team in conjunction with the requester and procurement specialist which addresses the

- Standards and requirements upon which the assessment will be based;

- Selection or development of an appropriate assessment checklist;

- Data available to support the assessment;

- Responsibilities of and relationships between the certified lead auditor, the requester, and the procurement specialist; and

- Assessment schedule.

Commercial Grade   A commercial grade item is an item that is

- Not subject to unique design requirements or specifications;

- Used in applications other than the requester's activities: and,

DEFINITIONS: *(cont.)*

- Subject to specifications set forth in a manufacturer's published catalog.

Desk Assessment

A desk assessment is an assessment that consists of a review of documents and/or of data without visiting the supplier's facility.

Finding

A finding is a deficiency in the supplier's QA program or other quality requirement which is documented in the assessment report and which requires a written response from the supplier of the corrective actions to be taken.

Objective Evidence

Objective evidence is any documented statement of fact, information, or record, either quantitative or qualitative, relating to the quality of an item or activity that is based on observations or tests, which can be verified.

Observation

An observation is a program weakness that is not necessarily related to specific quality requirements, but which could lead to a more serious deficiency, if not corrected. An observation does not constitute a lack of compliance (that is, a finding) nor does it require a written corrective action; however, it should be given serious consideration and documented in the assessment report. Observations may include noteworthy practices.

Site Assessment

A site assessment is an assessment that is conducted at a supplier's facility.

Supplier

A supplier is an individual or organization that intends to furnish items or services in response to a proposal or bid from the Laboratory.

PROCEDURES:

Quality-Affecting Procurements

A subcontract is considered to be quality-affecting when the Quality Assurance block on the *Purchase Request (PR)* (Form 838) (Rev. 1/95 or later) has been checked or there is any other indication on the *PR* that QA applies. See SI 46.1, Subcontract Quality Assurance, for further guidance.

QA Supplement

The procurement specialist must review Section I, Qualified Suppliers, of the *QA Supplement* (see Exhibit 46.1a). If the "Listing of Qualified Suppliers" block is checked, the requirements of this SI do not apply. The solicitation must be limited to the suppliers identified in the "Known Sources" field on the *PR* and/or on any separate documentation provided by the requester. Any addition or change to the bidders' list requires authorization from the requester.

PROCEDURES: *(cont.)* If the "Listing of Qualified Suppliers to be Determined in Conjunction with Procurement Quality Personnel" block is checked, the procedures in this SI apply. The procurement specialist should contact the BUS Quality Support Team (QST) for assistance.

> Note: The expense of qualifying a supplier will be charged to the requester.

Qualification Process What follows below is a description of the functions and responsibilities of the QST. QST will assign a lead auditor to

- Obtain data on the qualifications and performance of the supplier available from previous Laboratory assessments, DOE Contractor's Supplier Quality Information Group (SQIG), and/or the Government/Industry Data Exchange Program (GIDEP); and

- In conjunction with the requester, determine the type of assessment to be performed (site, desk, or SQIG).

If a site assessment is performed, the lead auditor will

- Request, obtain, and review the supplier's QA manual;

- Coordinate development of an assessment plan and checklist in conjunction with the requester and procurement specialist;

- Distribute copies of all relevant documentation, including the available performance history of the supplier to other team members;

- Issue timely written notification of the assessment schedule to the supplier, as well as a copy of the assessment plan;

- At the beginning of a site-visit, conduct an entrance meeting with appropriate levels of the supplier's management to

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PROCEDURES: *(cont.)*

- Advise them of the assessment scope and plan,
- Introduce the assessment team,
- Meet counterparts,
- Establish channels of communication, and
- Discuss the assessment sequence and plans for the exit meeting.

- Perform the assessment in accordance with the assessment plan and checklist;

- Verify that any corrective actions from previous assessments continue to be effectively implemented; and

- Conduct an exit meeting at the conclusion of the assessment with appropriate levels of the supplier's management to discuss results of the assessment and corrective actions, if any.

Checklist — The completed assessment checklist must

- Reference where in the supplier's QA program documentation each checklist criterion is addressed;

- Describe the objective evidence used to determine the status of each checklist criterion;

- Reference the objective evidence used to assess the QA program and identify, where appropriate, program applicability (e.g., ASME code, noncode safety related, commercial grade); and

- Use supplemental pages as necessary to record any additional data.

If a desk assessment is performed, the lead auditor will

- Request, obtain, and review either the supplier's QA Manual or available SQIG data and

- Evaluate the supplier's QA program based upon the manual, for compliance with NQA-1 or other standards in accordance with the desk assessment checklist or evaluate the SQIG data against the SQIG Assessment Evaluation Checklist.

PROCEDURES: *(cont.)*

Report

The lead auditor will issue a final report within ten working days of the completed assessment. The assessment report will include

- A summary of the assessment findings;

- A description of the supplier's scope of product or service covered under the assessed QA program(s);

- An assessment of the implementation of the supplier's QA program to include a description of any findings and, where possible, the potential impact on product or service quality. In the case of a desk assessment, a recommendation of the need for any supplementary assessment activities will be provided.

- For site assessments, an assessment of the implementation of corrective actions, if any, from previous assessments and a list of the key persons contacted during the assessment.

Corrective action responses to identified findings shall be requested from the supplier within 45 days of the issue date of the report.

Follow- Up

Assessment follow-up activities by the QST shall include the following:

- Review of any supplier corrective action responses for acceptability;

- Notification to the supplier of the results of the review; and

- Validation and verification of corrective actions.

Re-evaluation

The QST will perform a re-evaluation of each supplier on an annual basis. The re-evaluation shall consist of

- A desk assessment of any SQIG data available since the Laboratory's assessment;

PROCEDURES: (*cont.*)

- A telephone survey of the supplier to determine any significant changes in the supplier's organization or quality program; and

- A review of the supplier's performance since the last evaluation. This review will be based on information provided by the in-process and receiving inspections, procurement reviews, and other information gathered during the procurement process.

If significant concerns or changes are noted, the procurement specialist and the technical requester will be notified.

RESPONSIBILITIES:

Procurement Specialist

The procurement specialist must

- Evaluate the *PR* for the applicability of this SI and

- Obtain the support of the QST when the requester requires assistance in qualifying suppliers.

Quality Support Team

The QST must

- Assign a lead auditor;

- Coordinate and perform the assessment;

- Maintain supplier assessment records;

- Maintain the schedule of assessments;

- Develop, complete, and validate assessment checklists and periodically review checklists for adequacy; and

- Interface with the SQIG, maintain SQIG documentation, and provide input to SQIG database upon completion of assessment.

Lead Auditor

The lead auditor must lead, coordinate, and document all assessments requested by the procurement specialist or requester.

RESPONSIBILITIES:
(*cont.*)

Requester   The requester must

- Identify that a supplier needs to be prequalified by either contacting the QST and/or indicating that QA requirements apply on the *PR*;

- Determine the type of assessment required (i.e., desk or site);

- Provide technical support as needed and agreed upon during the planning of the assessment;

- Provide input on the appropriate checklist to use; and

- Identify the cost center and program code to be used for assessment expenses as agreed upon during the planning.